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KLARQUIST SPARKMAN, LLP
121 S.W. SALMON STREET
SUITE 1600
PORTLAND, OR 97204

EXAMINER	
SWOPE, SHERIDAN	
ART UNIT	PAPER NUMBER
1652	

NOTIFICATION DATE	DELIVERY MODE
07/26/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

tanya.harding@klarquist.com
docketing@klarquist.com

Office Action Summary	Application No.	Applicant(s)	
	10/590,844	HODGE ET AL.	
	Examiner	Art Unit	
	SHERIDAN SWOPE	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40 and 62-65* is/are pending in the application.

4a) Of the above claim(s) *64 and 65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40,62 and 63* is/are rejected.

7)☒ Claim(s) *40,62 and 63* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' Request for Continued Examination, filed January 20, 2010, is acknowledged. It is acknowledged that Claims 41, 48, 60, and 61 have been canceled, Claim 40 has been amended, and Claims 62-65 have been added. The elected invention is directed to a cellular method for identifying an agent that decreases pathogenicity of HIV-1 by decreasing Rab11A activity. Claims 40 and 62-65 are pending. Claims 64 and 65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. As amended, Claims 40, 62, and 63 are directed to a method for identifying an agent that decreases viral infection, which is a method distinct from the elected invention. Nonetheless, in the interest of public service Claims 40, 62, and 63 are hereby examined. Based or prior election and prosecution as well as the amendment of January 20, 2010, the currently examined invention is directed to a cellular method for identifying an agent that decreases HIV-1 infection.

Priority

The priority date granted for the invention recited in Claims 40, 62, and 63 is February 24, 2005, the filing date of PCT/US05/06396.

Claims-Objections

Claims 40, 62, and 63 are provisionally objected to for encompassing non-elected subject matter.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40, 62, and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

For Claim 40, "associating the level of viral infection with Rabl 1A gene expression or Rabl 1A activity" renders the claim indefinite because the term "associating" is unclear. The skilled artisan would not know the metes and bounds of the recited invention. Claims 62 and 63, as dependent from Claim 40, are rejected for the same reason.

Claims 40, 62, and 63 provide for the use of Rab11A; but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

The objective of the method recited in Claim 40 is to identifying an agent that decreases viral infection. As such the phrase "associating the level of viral infection with Rabl 1A gene expression or Rabl 1A activity, wherein a decrease in viral infection associated with a decrease of Rabl 1A gene expression, Rabl 1A activity, or a combination thereof indicates that the test agent is an agent that decreases viral infection" renders the claim indefinite because it is unclear how any steps encompassed by said phrase accomplish the objection of the recited method. The skilled artisan would not know the metes and bounds of the recited invention. Claims 62 and 63, as dependent from Claim 40, are rejected for the same reason. For purposes of examination, the phrase "associating the level of viral infection with Rabl 1A gene expression or Rabl 1A activity, wherein a decrease in viral infection associated with a decrease of Rabl 1A gene expression, Rabl 1A activity, or a combination thereof indicates that the test agent is an agent that decreases viral infection" is given no weight.

Any subsequent rejection based, on clarification of the above phrases and terms, will not be considered a new ground for rejection.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 40, 62, and 63 are rejected under 35 U.S.C. 101 because the claimed recitation of a use of Rab11A, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 40, 62, and 63 are rejected under 35 U.S.C. 112, first paragraph, for essentially the same reasons explained in the prior action. The specification, while being enabling for a method of identifying a pool of Rab11A siRNA oligonucleotides as inhibitors of infection by HIV in JC53-BL cells (Example 2; Fig 2), does not reasonably provide enablement for any biochemical, cellular, or in vivo method for identifying an agent that decreases infection of any cell by any virus or retrovirus.

In regards to this enablement rejection, the application disclosure and claims are compared per the factors indicated in the decision In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). These factors are considered when determining whether there is sufficient evidence to support a description that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. The factors include but are not limited to: (1) the nature of the invention; (2) the breath of the claims; (3) the predictability or unpredictability of the art; (4) the amount of direction or guidance presented; (5) the presence or absence of working examples; (6) the quantity of experimentation necessary; (7) the relative skill of those skilled in the art. Each factor is here addressed on the basis of a comparison of the disclosure, the claims, and the state of the prior art in the assessment of undue experimentation.

Claims 40, 62, and 63 are so broad as to encompass any biochemical, cellular, or in vivo method for identifying an agent that decreases infection of any cell by any virus or retrovirus. The scope of each of these claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of methods broadly encompassed by the claim. The specific reagents and steps used for any method determine the methods success. In the instant case, predictability of which steps and reagents can be used to obtain the desired identification of agents that decrease infection of any cell by any virus or retrovirus requires a knowledge of, and guidance with regard to how any said virus infects any said cell and how infection by any said virus can be detected. However, in this case the disclosure is limited to a method of identifying a pool of Rab11A siRNA oligonucleotides as inhibitors of infection by HIV in JC53-BL cells (Example 2; Fig 2).

While some methods for determining how to detect viral DNA and proteins as well as determining if a cell can be infected by a virus were known, it is not routine in the art to

determine how to detect infection by an essentially unlimited number of viruses in an essentially unlimited number of cells. Furthermore, the identity of methods for detecting viral DNA and proteins remained unpredictable for a variety of reasons including loss of anti-viral antibody production (Issaacson et al, 1995), choice of oligonucleotide to be used and spontaneous mutation of viral DNA and protein (Houng et al, 2000; pg 2, parg 2), isolation methods and sensitivity (Fuhrman et al, 2005; pg 4526, parg 1), viral protein conformation and antibody development (Kapaklis-Deliyannis et al, 1993; parg brd pg 935-6), and environmental factors (Lewis et al, 2000; pg 638, parg 2). Thus, the artisan is reduced to trial and error making and testing of reagents and steps for detecting any virus in any cell.

The specification does not support the broad scope of Claims 40, 62, and 63, which encompass all biochemical, cellular, and in vivo methods for identifying an agent that decreases infection of any cell by any virus or retrovirus. The specification does not support the broad scope of Claims 40, 62, and 63 because the specification does not establish: (A) steps and reagents for detecting infection of any cell by any virus or retrovirus; (B) how any successful method may, or may not, be altered without affecting the desired analysis; (C) the general tolerance of any successful method to modification and extent of such tolerance; (D) a rational and predictable scheme for developing successful methods for detecting infection of any cell by any virus or retrovirus; and (E) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of methods for identifying an agent that decreases infection of any cell by any virus or retrovirus. The scope of the claims must bear a reasonable

correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of sequences having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

In support of their request that the prior rejection be withdrawn, Applicants provide the following arguments. These arguments are not found to be persuasive for the reasons following each argument.

(A) Any necessary experiment is merely routine, and thus not undue.

(A) Reply: It is acknowledged that a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. In the instant case, the amount of experimentation is undue for the reasons stated above.

(B) The specification provides numerous exemplary methods for identifying agents that decrease viral infection by monitoring Rabl 1A activity or expression, including page 39, line 16 - page 41, line 28, Example 13 and Example 14. All of these methods are routine and known to those of ordinary skill in the art. Therefore, it is believed that any experiment is well within the limits set by the Genentech court. As such, Applicants believe that the claims as presented herein are fully enabled by the specification and satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph.

(B) Reply: This argument is not relevant to the instant rejection because, as explained above, the phrase "associating the level of viral infection with Rabl 1A gene expression or Rabl 1A activity, wherein a decrease in viral infection associated with a decrease of Rabl 1A gene

expression, Rabl 1A activity, or a combination thereof indicates that the test agent is an agent that decreases viral infection" is indefinite and is given no weight.

For these reasons and reasons explained in the prior actions, Claims 40, 62, and 63 are rejected under 35 U.S.C. 112, first paragraph/enablement.

Written Description

Claims 40, 62, and 63 are rejected under 35 U.S.C. 112, first paragraph, for essentially the same reasons explained in the prior action. Claims 40, 62, and 63 are directed to a genus of any biochemical, cellular, or in vivo method for identifying an agent that decreases infection of any cell by any virus or retrovirus. The specification teaches a single representative species of such methods. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of being a means for identifying an agent that decreases infection of any cell by any virus or retrovirus. Given this lack of description of representative species encompassed by the genera of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

In support of their request that the prior rejection be withdrawn, Applicants provide the following argument. This argument is not found to be persuasive for the reasons following the argument.

(A) As stated above, specification provides written support for numerous exemplary methods for identifying agents that decrease viral infection by monitoring Rabl 1A activity or expression, including page 39, line 16 - page 41, line 28, Example 13 and Example 14.

(A) Reply: As stated above, this argument is not relevant to the instant rejection because, as explained above, the phrase "associating the level of viral infection with Rabl 1A gene expression or Rabl 1A activity, wherein a decrease in viral infection associated with a decrease of Rabl 1A gene expression, Rabl 1A activity, or a combination thereof indicates that the test agent is an agent that decreases viral infection" is indefinite and is given no weight.

For these reasons and reasons explained in the prior actions, Claims 40, 62, and 63 are rejected under 35 U.S.C. 112, first paragraph/written description.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40, 62, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Pannecouque et al, 2002. Pannecouque et al teaches a cellular method, using both antibody detection and PCR, for identifying an inhibitor of HIV-1 replication (pg 1176, parg 2; Table 1 Fig 2 & 4). Therefore, Claims 40, 62, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Pannecouque et al, 2002.

Claims 40, 62, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al, 2003. Lin et al teaches a method for identifying an inhibitor of HIV-1 of entry using a luciferase reporter assay and a binding assay (Fig 1 and 2). Therefore, Claims 40, 62, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al, 2003.

Allowable Subject Matter

No claims are allowable.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Any new references were cited solely to support rejection(s) based on amendment or rebut Applicants' arguments. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages. It is also requested that the serial number of the application and date of amendment be referenced on every page of the response.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/
Primary Examiner, Art Unit 1652